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September 5, 2013

VIA E-FILE & HAND DELIVERY

The Honorable Sue L. Robinson
United States District Court – District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street, Room 4124, Unit 31
Wilmington, DE 19801

Re: *Takeda Pharmaceuticals U.S.A, Inc. v. Amneal Pharmaceuticals, LLC*,
C.A. No. 13-493 (SLR)

Dear Judge Robinson,

We write in follow-up to Par's September 4, 2013 letter to Your Honor in related case 12-cv-00419, to inform the Court of a significant upcoming change to Amneal's colchicine ANDA that is currently the subject of litigation pending before the Court in the above captioned case. On August 28, 2013, Amneal informed Takeda that it would be amending its colchicine ANDA application in a manner similar to what Par had done: namely, Amneal will be changing the indication for which it is seeking regulatory approval from "gout" to "FMF" (Familial Mediterranean Fever). We wish to confirm for the Court that Amneal is diligently preparing the FDA regulatory paperwork for making this change, and currently anticipates that the paperwork will be completed and filed with the FDA by the end of next week. Amneal will concurrently be providing Takeda with a revised PIV certification letter reflecting this change and addressing the necessary Orange Book patents, as was done previously by Par.

The practical consequence of this change is that 12 of the 14 patents currently in suit in the above captioned case will no longer be at issue, and the three new FMF patents now in suit in the new Par case (13-cv-01524) will also become, in due course, the subject of litigation against Amneal. The five patents in suit for FMF in the new Par case will be the same as the patents in suit for Amneal upon completion of Amneal's regulatory filing and new certification.

In view of this impending change, Amneal believes that it may be beneficial for the Court to conduct a status conference involving all parties to determine the best way to proceed forward with scheduling and discovery.

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Respectfully submitted,

/s/ Mary B. Matterer

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MBM/kjh
cc: All counsel of record (via email and CM/ECF)